DIA Workshop
DRAFT
GUIDANCE FOR INDUSTRY: Regulatory Submissions in Electronic Format

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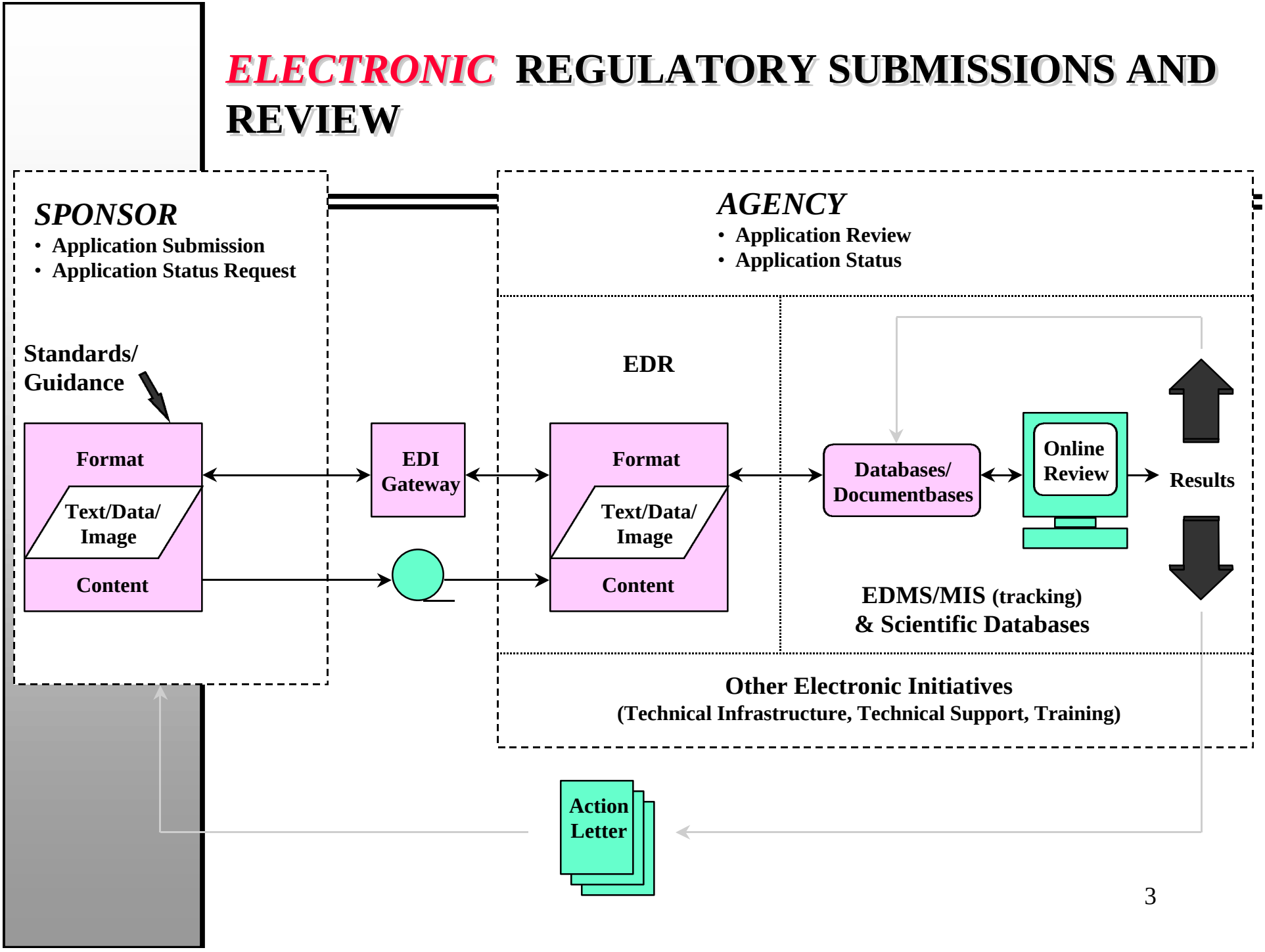
First the Big Picture...

- Electronic Regulatory Submission and Review (ERSR) model
- ERSR goals
- ERSR influences and expectations

ELECTRONIC REGULATORY SUBMISSIONS AND REVIEW



CDER's ERSR Goals for 2002

- All submissions can be received and archived electronically
- All electronic submissions, reviews, and other related information can be accessed by the reviewer through a desktop computer
- Automated routine data analysis, and
- Publicly available info is on the Internet

Influences and Expectations

- Influences
  - costs, recent legislation and regulations
  - impact e-information already has on review
  - international harmonization
- Expectations
  - meet our mandates
  - reduce costs
  - disaster recovery
  - increase info accessibility, use, and exchange

Today's Focus

- CDER's draft guidance for providing NDAs in electronic format
  - overview of the guidance
  - expanded discussion of key sections in presentations later today
  - wrap-up with a Q&A panel

Organization and Highlights of the Guidance by Section

- Introduction
- Background
- Archival Copy in Electronic Format
- Archival Copy in Paper Format
- Review Copy
- Supplements and Amendments
- Review Aids
- Sending Submissions to CDER
- Technical Support

Section I: Introduction

- Describes the purpose of the guidance
- Reviews the role of Part 11:
  - voluntary submission of the document types we publish in the public docket
  - the guidance reduces your need to consult with CDER

Section II: Background

- Impact on CFR 314
  - requires an archive, review, and field copy
  - the field copy is not addressed by this guidance
- After final review CDER only retains the archive copy of all submissions
- The electronic archive copy can serve as the primary source for review
- Other document types will follow
  - ANDAs, INDs, DMFs, etc

Section III: Archival Copy in Electronic Format

- File formats and organization for electronic documents and data sets
  - reasons for the formats selected
  - recommendations for preparing information in these formats
- Provides regulatory references and organizational needs for each NDA item

Section IV:
Archival Copy in Paper Format

- Its your option to replace the paper archive with an electronic one provided that:
  - the document type is identified in the docket
  - you consulted the receiving unit on the method of transmission, media, file formats, etc. they can handle (OIT is CDER's receiving unit)
- Submissions may include a mixture of paper and electronic parts for archive

Section V: Review Copy

- The electronic archive copy can serve as the primary source for review
  - the need for a paper review copy of many parts has been eliminated
- For now, we still need paper review copies for certain heavily read parts of the NDA
- Review divisions may elect to eliminate additional portions of the paper review copy

Section VI: Supplements and Amendments

- Items identified in the NDA can also be submitted electronically with amendments and supplements

Section VII: Review Aids

- In addition to the archive and review copies, you can supply ‘review aids’
  - word processor formats, and customized systems and tools for handling documents and data
- Review aids are considered case-by-case by review divisions
  - Handled as ‘Desk Copies” that are receive in addition to the archive and review copies
- Review divisions must consult with OIT before accepting review aids that require changes to CDER’s PCs, use of CDER’s network, or OIT staff

Section VIII: Sending Submissions to CDER

- Describes what and when to submit:
  - directly to CDER's Central Document Room (CDR), and
  - directly to review divisions
- Describes the types of media that CDER can handle, and how to prepare the media for submission

Section IX:
Technical Support and Questions

- Mr. Ken Edmunds, Electronic Submissions Coordinator
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